

10/6/2015 2:14 pm

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X
UNITED STATES OF AMERICA,

-against-

WILLIAM SCULLY, also known as "Liam
Scully,"

Defendant.
-----X

**DECISION AND ORDER
ON MOTION IN LIMINE**
14-cr-208(ADS)

**U.S. DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
LONG ISLAND OFFICE**

APPEARANCES

**OFFICE OF THE UNITED STATES ATTORNEY
FOR THE EASTERN DISTRICT OF NEW YORK**

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SPATT, District Judge:

On September 14, 2015, the Government made a motion *in limine*, seeking *inter alia* to preclude the Defendant William Scully a/k/a Liam Scully ("Scully" or the "Defendant") from asserting the affirmative defense of advice of counsel. In particular, the Government contended that Scully is unable to establish one or more elements of the advice-of-counsel defense and, therefore, should not be permitted to present any related evidence at the trial.

On October 1, 2015, pursuant to the authority of United States v. Paul, 110 F.3d 869 (2d Cir. 1997), and its progeny, this Court ordered that an evidentiary hearing be held to determine whether sufficient questions of fact exist to warrant permitting the jury to hear evidence of the advice-of-counsel defense.

On October 5, 2015, the Court held a hearing (the “Hearing”) at which the Government presented evidence in support of its motion *in limine*. At the conclusion of the Government’s presentation, Scully made an oral application to deny the Government’s motion, without requiring the defense to present evidence on his behalf. In this regard, Scully asserted that the Government’s evidence was insufficient to establish that his advice-of-counsel defense would fail as a matter of law and, thus, the defense should not be dismissed and should be presented to the jury.

The Court reserved decision on Scully’s oral motion and ordered that the Hearing be continued on October 6, 2015 at 10:00 A.M.

At this time, for the reasons contained in this Decision and Order, the Court grants Scully’s oral application and denies the Government’s motion *in limine* to the extent it seeks to preclude the presentation of any evidence in support of an advice-of-counsel defense at the trial.

I. The Hearing

The Government called only one witness to testify at the Hearing, namely, Special Agent Matthew Comerford of the federal Food and Drug Administration’s (“FDA”) Office of Criminal Investigations. Agent Comerford stated that he

participated in the execution of a search warrant upon the offices of Pharmalogical, Inc. d/b/a Medical Device King and MDK (“Pharmalogical”) on May 24, 2012. As such, Agent Comerford offered testimony as to the authenticity of various items of documentary evidence recovered during the search. Many of the Government’s exhibits were offered into evidence without objection. Scully objected to others, and the Court issued evidentiary rulings on such objections on the record. Unless otherwise noted, in this opinion, the Court will refer to the Government’s documentary evidence as “Government Hearing Exhibits,” which will be abbreviated as “GHE.”

At the outset, the Court emphasizes that Agent Comerford, the only witness for the prosecution, was solely an authenticating witness to the search. In this regard, the Court notes that Agent Comerford had little, if any, personal knowledge relating to the content of any of the Government Hearing Exhibits or the underlying facts and circumstances in this case. Further, the Government presented no other fact witnesses whose testimony would have strengthened the legal inferences sought to be drawn by the Government. Rather, as will be discussed in this opinion, beyond the authentication of approximately 19 pieces of documentary evidence, the Government’s entire presentation consisted of an attorney argument as to the meaning and legal import of the documents in the record.

A. The Standard for an “Advice of Counsel” Defense

“To benefit from an advice-of-counsel defense, a party must show that he (1) ‘honestly and in good faith’ sought the advice of counsel; (2) ‘fully and honestly la[id]

all the facts before his counsel'; and (3) 'in good faith and honestly follow[ed]' counsel's advice, believing it to be correct and intending that his acts be lawful." United States v. Colasuonno, 697 F.3d 164, 81 (2d Cir. 2012) (quoting Williamson v. United States, 207 U.S. 425, 453, 28 S. Ct. 163, 52 L. Ed. 278 (1908)). "Each requirement must be satisfied." Id.

B. Summary of the Government's Position

At the Hearing, the Government advanced a three-part argument challenging Scully's ability to satisfy all three separate elements of this defense. First, the Government contends that Scully did not honestly and in good faith seek the advice of his attorneys because he engaged in the allegedly criminal activities giving rise to the charges against him *prior* to consulting his attorneys. In particular, the Government contends that Scully sought after-the-fact legal opinions to use as a "sales tool" to apparently assuage the concerns of potential customers over the legality of his business practices and as a defense to a criminal prosecution.

Second, the Government contends that Scully did not fully and honestly lay all of the relevant facts before his counsel. On the contrary, the Government asserts that Scully withheld pertinent facts from his attorneys relating to, among other things, his understanding as to whether his business practices complied with the applicable FDA regulations; his understanding as to the legality of the drugs and medical devices he was selling; and his methods of importing the subject drugs and medical devices into the United States.

Third, the Government contends that Scully did not honestly and in good faith follow the advice of his counsel. Rather, the Government contends that Scully continued his illegal sales activities through Pharmalogical and a second company, Taranis Medical Corp. (“Taranis”), even after being advised not to do so by his attorneys.

II. The Applicable Legal Standard

The law is clear that a district judge may preclude an affirmative defense by granting a motion *in limine*. See United States v. Crown, 99-cr-1044, 2000 U.S. Dist. LEXIS 7443, at *3 (S.D.N.Y. May 31, 2000), aff’d, 12 F. App’x 59 (2d Cir. 2001) (citations omitted). “The sole question presented in such situations is whether the evidence, as described by the defendant, is insufficient as a matter of law to support the proffered defense.” Id. (citing United States v. Aguilar, 883 F.2d 662, 692 (9th Cir. 1989)). Of importance, “[e]vidence should be excluded on a motion *in limine* only when the evidence is clearly inadmissible on all potential grounds.” Wechsler v. Hunt Health Sys., 94-cv-8294, 2003 U.S. Dist. LEXIS 14592, at *7 (S.D.N.Y. Aug. 22, 2003) (citing Baxter Diagnostics, Inc. v. Novatek Medical, Inc., 94-cv-5220, 1998 U.S. Dist. LEXIS 15093, at *11 (S.D.N.Y. Sept. 25, 1998)). As discussed more fully in this opinion, the Court finds that the evidence submitted thus far does not establish that Scully’s advice-of-counsel defense is insufficient as a matter of law.

III. Discussion

In the Court’s view, the Government’s evidence is sufficient to raise an inference that the facts of this case do not support an advice-of-counsel defense.

However, the Court finds that the evidence is largely disputed; that the Defendant contests the meaning attributed by the Government to virtually every item of documentary evidence; and that, at least at this juncture and without the benefit of any meaningful witness testimony, the evidence is susceptible of more than one reasonable interpretation. As a result, the Court discerns numerous potential factual issues of varying magnitudes, which, in the Court's view, require adjudication by a jury and not by this Court on a motion *in limine*.

Stated otherwise, the Court is unable to conclude on the record before it that the evidence is so contrary to Scully's contentions that he should be precluded from presenting his alleged reliance on his counsel's advice to the jury. Further, the Court finds that this outcome is warranted without requiring Scully to present witnesses or testify himself in this *in limine* Hearing.

A. The First Element – As to Whether Scully Honestly and In Good Faith Sought the Advice of Counsel

As to the first element of the advice-of-counsel defense, namely, that Scully honestly and in good faith sought the advice of counsel: The Government contends that Scully was engaged in the illegal sales of cosmetic, contraceptive, and oncology products prior to having any consultation with his counsel, the law firm of Thaler & Gertler, LLP (the "Firm"), as to the legality of his actions. For this conclusion, the Government relies on apparent discrepancies between the Firm's billing records and invoices generated by Pharmalogical. In particular, a January 12, 2008 invoice from Pharmalogical reflects the sale of Botox. See GHE #1. However, the Firm's billing records indicate an initial consultation with Scully in December of 2008. See

GHE #4. Therefore, the Government contends that Scully could not have consulted with his attorneys regarding the legality of selling Botox because he was engaged in that activity almost one year before his initial consultation. However, there is no evidence that the Botox purportedly sold by Scully on January 12, 2008 was illegal or defective in any way, so that an opinion of counsel as to its legality would have been required. On the contrary, Scully asserts that Pharmalogical was a licensed wholesaler of such products in New York State and that, absent Government evidence to the contrary, Pharmalogical's sales constitute normal and legal operations within the scope of its license.

The Government further relies upon a lengthy gap in the Firm's billing records to support its contention that Scully was not seeking the advice of his counsel during that period. In particular, a November 2, 2009 invoice from Pharmalogical reflects the sale of a contraceptive product, more specifically, an intrauterine device known as Mirena ("Mirena"). See GHE #2. However, the Firm's billing records do not indicate any legal services billed to Scully's account between October 9, 2009 and May 10, 2010. See GHE #4. According to the Government, this evidence demonstrates that Scully began illegally selling Mirena without first being in consultation with the Firm. Further, the Government asserts that Scully had no contact with his attorneys until approximately six months after his sale of Mirena on November 2, 2009, and that the first mention of Mirena in the Firm's records does not appear until several days later.

Similarly, the Government relies upon a June 6, 2011 invoice from Medical Device King, an alleged alias of Pharmalogical, reflecting the sale of drugs known as Gemzar and Eloxatin, which the Government represented to the Court are cancer treatment medications. See Govt. Trial Ex. “11”. However, again, the Firm’s billing records indicate a gap in services rendered to Scully’s account from November 5, 2010 to October 18, 2011. See GHE #4. Thus, the Government urges the conclusion that Scully was engaged in the illegal sale of these oncology drugs without first consulting his attorneys.

In response, Scully challenges the propriety of this inferential reasoning. He asserts that the apparent gaps in the Firm’s billing records could be attributable to any number of potential causes. For example, Scully asserts that the records relating to attorney Gertler, a partner in the Firm, do not account for communications he had during these time periods with other counsel, including one Peter Tomao, Esq., a criminal law expert. Scully contends that this evidence, without more, is insufficient to establish, as a matter of law, that he did not honestly and in good faith seek the advice of his counsel. The Court agrees. The Court is of the view that, under the applicable law, a jury, and not this Court, should resolve the factual issues raised by the parties, and to decide the appropriate meaning to be given to the evidence in the record.

Accordingly, to the extent the Government seeks to preclude an advice-of-counsel defense on the ground that the evidence in support of the first element –

namely, whether Scully honestly and in good faith sought the advice of counsel – is insufficient as a matter of law, its motion is denied.

B. The Second Element – As to Whether Scully Fully and Honestly Provided All of the Relevant Facts to His Attorneys in Seeking Advice

As to the second element of the advice-of-counsel defense, namely, that Scully fully and honestly laid all of the pertinent facts before his counsel: The Government contends that Scully had meaningful and relevant communications with the FDA that he failed to disclose to his attorneys. In particular, the Government relies upon a March 8, 2010 e-mail from Scully to the Center for Drug Evaluation and Research (“CEDR”), a sub-group of the FDA. In this email, which bears the subject “RE: 03-096 cmh Mirena,” an unidentified employee of the FDA wrote, in pertinent part, as follows:

Thank you for writing the Division of Drug Information, in the FDA’s Center for Drug Evaluation and Research.

The United States Federal Food, Drug, and Cosmetic Act (21 USC ‘ 331) prohibits the interstate shipment and importation of unapproved new drugs. An unapproved new drug is any drug, including a foreign-made version of a U.S. approved drug, that has not been manufactured in accordance with an FDA approval. The product you are wishing to import is considered an unapproved drug product.

See GHE #8.

The Government asserts that this communication took place months before Scully first discussed the legality of selling Mirena with his attorneys.

In addition, an FDA phone log reflects that an employee named C. Chang spoke with a caller named “Liam” on the telephone the very next day, March 9, 2010. Chang’s notes from the conversation read as follows:

caller wanted to buy repackaged mirena with non-approved package insert and labeling and sell in US
caller became irate when I told him that, since the NDA [New Drug Application] process is not met, such practice is not feasible. He claims that other repackagers are doing it and that it’s okay then proceeded to hang up on me.

See GHE #8.

The Government contends that these communications demonstrate that the FDA informed Scully that his business practices were illegal. Nevertheless, according to the Government, Scully subsequently sought legal opinions on the exact same subject matter without disclosing his communications with the FDA to counsel. The Government points to various portions of legal memoranda prepared by the Firm to demonstrate that Scully withheld such information. In particular, a May 21, 2010 opinion letter prepared by attorney Gertler on behalf of the Firm indicates that “Pharmalogical, through Mr. Liam Scully” had advised the Firm of several facts that were used in formulating the Firm’s opinions, including, *inter alia*, that “Pharmalogical follows all laws and regulations governing importing Mirena into the USA.” See GHE #10.

Also, in a February 16, 2012 letter, attorney Gertler states that Scully:

[A]dvised [the Firm] that Pharmalogical purchases certain prescription drugs from one or more European manufacturers of the drugs located in Ireland and the United Kingdom, that these manufacturers are fully authorized to manufacture and sell the drugs in Ireland and the UK, and that these drugs, as well as the Irish and UK manufacturers who

sell them to Pharmalogical and the packaging of these products, have been approved by the FDA.

See GHE #14.

The Government asserts that these statements, purportedly made by Scully to his counsel in order to obtain a legal opinion, are false because the FDA had already informed him that Mirena was unapproved and prohibited from being legally imported. According to the Government, Scully also misrepresented that he purchased the drugs from Ireland and the United Kingdom and that he purchased drugs directly from the drug manufacturers.

In opposition, Scully raises several factual issues with regard to the records of his purported communications with the FDA. Initially, he notes that the March 8, 2010 e-mail includes a disclaimer, stating that the communication “constitutes an informal communication that represents [the FDA’s] best judgment at th[at] time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.” See GHE #10. Thus, Scully contends, the author’s opinion as to the legality of his actions did not necessarily reflect the actual position of the FDA.

With respect to the call log created by C. Chang on March 9, 2010, Scully points out that the references to “repackaged mirena” and the New Drug Application Process demonstrate a clear miscommunication between Scully and Chang. In this regard, Scully asserts that Pharmalogical did not sell repackaged Mirena; that the New Drug Application is irrelevant to Scully’s actions in this case;

and that Chang obviously did not understand the nature of Scully's inquiry. At the Hearing, defense counsel suggested that any reasonable person would have become "irate" under similar circumstances.

Scully also relies on the following e-mail, dated March 3, 2010, which he wrote to an FDA sub-group under the subject heading "Mirena":

After speaking with you today on the phone, I just wanted to get confirmation via email as well that purchasing the identical device (that is already approved in the U.S.) from the manufacturer or one of their distributors overseas, is not in violation of any U.S. laws. The product we discussed is the Mirena device and the only difference is that there is some different language on the box, but the device is identical and is manufactured in the same facility in Finland. Thank you.

See GHE #8.

It is Scully's contention that this confirmatory e-mail to the FDA suggests that he had received a representation from the FDA earlier that day over the telephone that his actions were not in violation of any federal laws. This purported conversation took place before he received a conflicting response on March 9, 2010, that his actions were illegal. He asserted at the Hearing that, in light of these apparently conflicting responses from the FDA, he sought legal advice to obtain a definitive opinion as to the legality of his actions. According to Scully, the fact that he sought advice from counsel after receiving inadequate responses from representatives of the FDA does not support a finding that the advice-of-counsel defense should be precluded as a matter of law.

Finally, the Government relies upon a series of e-mails involving one Ozkan Semizoglu, a Turkish national and representative of Ozay Pharmaceuticals, which

is based in Turkey and allegedly engaged in business with Pharmalogical. See GHE #12. According to the Government, these e-mails, which span the period of time from June 24, 2011 to February 1, 2012, demonstrate that Pharmalogical, in conjunction with Ozay Pharmaceuticals, illegally smuggled the subject drugs and medical devices into the United States. In particular, the e-mails appear to reference bribing customs officials; spacing deliveries one day apart to avoid detection by customs officials; and similar nefarious behavior. The Government asserts that Scully withheld from his attorneys these important facts regarding the manner in which Pharmalogical's products were imported in seeking their legal opinions.

In opposition, Scully contends that he was not involved in these e-mail communications, which appear to have taken place primarily between Semizoglu and Scully's business partner, Rodi Lameh. He denies ever engaging in such conduct, and, thus, asserts that he did not possess knowledge of these facts to share with his attorneys.

On this record, the Court is of the view that a reasonable jury could conclude that Scully withheld material facts from his attorneys. However, the Court is not persuaded that the evidence is so one-sided in the Government's favor that Scully should be precluded altogether from presenting his account of these events to the jury. Accordingly, to the extent the Government seeks to preclude an advice-of-counsel defense on the grounds that the evidence in support of the second element is insufficient as a matter of law, its motion is denied.

C. The Third Element – As to Whether Scully Honestly and In Good Faith Followed Counsel’s Advice

In the Court’s view, the Government’s position is weakest as it relates to the third element, namely, whether Scully followed his counsel’s advice honestly and in good faith and intended that his acts be lawful. In this regard, the Government presented numerous documents that it contends reflect advice by Scully’s lawyers that he was, in one form or another, acting in violation of relevant laws, rules, and regulations. For example, the Government relies upon a June 8, 2012 memorandum prepared by one Kathy Wetterhahn, a paralegal at the Firm, to attorney Gertler, in which she appears to conclude, *inter alia*, that “since the drugs at issue do not bear the ‘Rx only’ label, they are considered ‘misbranded’ and subject to seizure if they were offered for sale in the U.S.” See GHE #15. However, as Scully asserted at the Hearing, the Court sees no basis for equating the opinions of a paralegal to a partner of the Firm with advice given by the Firm to Scully. There is no evidence showing that attorney Gertler adopted Wetterhahn’s conclusions and conveyed them to Scully as legal advice.

The Government also relies on communications between Scully and one Geoffrey Kaiser, Esq. Initially, it warrants noting that the Court heard conflicting statements regarding Scully’s relationship to attorney Kaiser which, in the Court’s view, itself requires this question to be placed before the jury. In particular, the Government asserted that Kaiser jointly represented Scully and his partner, Lamah. Scully disputed this, contending that Kaiser did not represent him. Agent Comerford testified that documents in evidence appeared to demonstrate that

Kaiser is an attorney, but had no personal knowledge of whether he represented Scully. In any event, the record contains communications that the Government contends indicate legal advice from attorney Kaiser that Scully ignored.

First, on June 19, 2012 Kaiser sent an e-mail to attorney Tomao, attorney Gertler, Scully and Lamah, stating that “Liam was going to send a separate spreadsheet listing the onco drugs, but if they don’t have the ‘Rx only’ designation, we will not be able to challenge the agent’s claim that they are misbranded in any event.” See GHE #16. Next, on August 6, 2012, Kaiser wrote the following to the same group of individuals with regard to a cease and desist letter from a competing drug company called Medicis:

But Medicis’s claims do highlight something that we have discussed many times before, and that is the importance of ensuring that the products you sell are FDA-compliant in all respects, as well as the wisdom of consulting FDA regulatory counsel to ensure that everything you are doing in marketing your products complies with FDA regulatory requirements.

See GHE #18.

The Government contends that Scully failed to follow attorney Kaiser’s advice in several ways. On the one hand, Scully failed to consult an FDA regulatory expert; and on the other hand, in spite of counsel’s advice to ensure FDA compliance in all respects, Scully also continued to sell misbranded products. In this regard, counsel for the Government repeated to the Court at the Hearing that Scully “kept selling” these illicit products. However, on the record before it, the Court is not convinced that this contention is accurate. In fact, in the Court’s view, there is apparently no evidence that Scully sold any products that failed to comply with

FDA regulations either before or after receiving this purported advice of counsel. Certainly, Agent Comerford did not provide any testimony in that regard and, in the Court's view, beyond the prosecutors' oral representations, the current record does not contain any supporting evidence that would warrant granting the Government's motion on this ground.

Of importance, with respect to the instant motion *in limine*, the Court notes that attorney Gertler, on May 21, 2010, wrote a nine-page opinion letter, which included the following paragraph:

PERSONAL & CONFIDENTIAL
ATTORNEY-CLIENT PRIVILEGE
ATTORNEY WORK PRODUCT

Based on the information which, as set forth above, Pharmalogical's actions would not violate the following criminal laws of the United States: Trafficking in Counterfeit Trademarks, Service Marks, or Certification Marks, 18 U.S.C. § 2320(a), Criminal Copyright Infringement, 17 U.S.C. § 506(a) and 18 U.S.C. § 2319, and the Federal Food, Drug and Cosmetic Act (FDCA), 18 U.S.C. § 331 *et seq.*, as well as the federal anti-fraud statutes, such as Title 18, United States Code Sections 1341 (mail fraud), 1343 (wire fraud) and 1349 (fraud conspiracy).

See GHE #10.

The Court also takes into consideration the apparent facts that Scully consulted his attorneys at almost every stage; that he did so voluntarily and at his expense; that he received opinions on all of these occasions; and that, at least according to his attorneys, he followed counsel's advice.

Accordingly, to the extent the Government seeks to preclude an advice-of-counsel defense on the grounds that the evidence in support of the third element is insufficient as a matter of law, its motion is denied.

IV. Conclusion

For the reasons contained in this Decision and Order, the Government's motion *in limine* is denied and the Defendant is not precluded from asserting a defense of advice of counsel at his trial.

Jury selection shall proceed as scheduled on Wednesday, October 7, 2015 at 9:00 A.M. before United States Magistrate Judge Steven I. Locke.

SO ORDERED

Dated: Central Islip, New York
October 6, 2015

/s/ Arthur D. Spatt
ARTHUR D. SPATT
United States District Judge